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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,428	08/07/2001	Lei Wu	4718420005000	3614
25225 7590 10/03/2008 MORRISON & FOERSTER LLP 12531 HIGH BLUFF DRIVE SUITE 100 SAN DIEGO, CA 92130-2040			EXAMINER CHEU, CHANGHWA J	
			ART UNIT 1641	PAPER NUMBER
			MAIL DATE 10/03/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/924,428	Applicant(s) WU ET AL.	
	Examiner JACOB CHEU	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14, 33, 34, 56, 67, 118, 119 and 122-139 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14, 33-34, 56, 67, 118-119 and 133-139 is/are rejected.
- 7) ☒ Claim(s) 122-132 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of Claims

Applicant's amendment filed on 5/12/2008 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 1-13, 15-32, 35-55, 57-66, 68-117 and 120-121 have been cancelled.
2. Claims 133-139 have been added to the instant application.
3. Currently, claims 14, 33-34, 56, 67, 118-119 and 122-139 are under examination.

Withdrawn Allowable Subject Matters

1. The allowable subject matters indicated in the previous Office Action (mailed on 1/10/2008) have been withdrawn in light of new cited reference (See below).

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 122-132 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 122, it is not clear what is the relationship of the binding partner to the microdevice. In another word, it is not clear where the binding partner located. It appears from specification that the binding partner is immobilized on the substrate. Applicant needs to clarify it.

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With respect to claim 122, it is not clear whether the “photorecognizable pattern” is the same with the “patterned magnetic material”. According to Figure 13 of the specification, it appears that the magnetic layer and its fabrication correspond to the recognizable holes. Applicant needs to clarify.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 14, 33-34, 118-119 and 133-135, 138-139 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaye et al. in view of Wu et al., Hasegawa et al. (US 5858125) and Hungerford et al. (US 20020034042).

Kaye et al. teach a microdevice for combinational library screening. Kaye et al. teach that the microdevice comprises a substrate, a photorecognizing coding pattern on said substrate, and a binding partner for binding target molecule of interest (See page 6, line

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5-15; page 2, line 1-5; Figure 2 and 5). The microdevice can be conjugated with *beads* where the interest of target is immobilized thereon for screening (See page 19, line 12-20; Figure 7, particular Figure 7b)(emphasis added). The target molecules immobilized on the microdevice, includes peptide, compounds, or oligonucleotides suitable for combinatorial synthesis or analysis (See page 1, first paragraph; page 3-4; page 18, line 15-20). These peptides, compounds or oligonucleotides are inherent binding partners capable of being manipulated. The photorecognizable code taught by Kaye et al. consists of different shapes and forms, including hollows, grooves, or notches, which are holes not penetrating through the entire depth of the substrate (See page 6, line 5-15; Figure 2 and 5; *Particular Figure 2, second example, holes not penetrated through the substrate*)(emphasis added). Kaye et al. also teach use of silicon layer for the substrate (See Abstract). With respect to the dimensions, the microdevice taught by Kaye et al. can be within from 1 to 500 microns ranges (See page 9, last paragraph). The microdevice of Kaye et al. does not comprise an anodized metal surface layer (See page 10-15; Figure 2-5;). However, Kaye et al. do not disclose the features of having magnetic material on the microdevice. Furthermore, Kay et al. do not explicitly teach using material, such as nickel or CoTaZr alloy for the substrate layer.

Wu et al. teach immobilizing binding partner capable of being manipulated on the beads having magnetic materials (See Figure 4). Wu et al teach using magnetic force or means for detection or separation of analyte from the sample. Supra. It is known and common practice in the art using magnetic means for detection analyte.

Hasegawa et al. teach that the CoTaZr alloy provides advantage for increasing magnetoresistance sensitivity for magnetic sensor (Col. 2, line 35-41).

Hungerford et al. teach that the nickel-zinc ferrite also provides advantage for increasing magnetoresistive sensor (See Section 0036).

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Therefore, it would have been prima facie obvious to one ordinary skill in the art at the time the invention was made to have motivated Kaye et al. to use the magnetic beads as taught by Wu et al. detection or separation of analyte in a sample. One ordinary skill in the art would have been motivated to use the magnetic means in order to improve efficiency of detection, separation or isolation of target molecules from the sample.

Furthermore, it would have been obvious to one ordinary skill in the art at the time the invention was made to have motivated Kay and Wu et al. to use either nickel metal or CoTaZr alloy as taught by Hasegawa or Hungerford et al. in order to take the advantage of enhancing the sensitivity of magnetic means detection.

With respect to claims 33-34 and 134-133, Kaye teach using fluorescent or phosphorescent materials substance for detection purpose (See page 15, line 20).

With respect to claims 118-119 and 138-139, Kaye et al. teach that the thickness of the microdevice is about 10 microns (See page 21, last paragraph).

With respect to claim 133, Wu et al. teach immobilizing antibody on the magnetic beads (See Figure 3; Abstract).

4. Claims 56, 67 and 136-137 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaye et al. in view of Wu, Hasegawa et al. and Hungerford et al. and further in view of Zhou et al.

Kaye, Wu, Hasegawa and Hungerford et al. references have been discussed but are silent in teaching use of chips for analysis.

Zhou et al. teach a biochip to detect manipulation of micro-particles and biological materials for economy and time-saving purposes (Col. 2, line 55-65).

Therefore, it would have been prima facie obvious to one ordinary skill in the art at the time the invention was made to have motivated Kaye, Wu, Hasegawa et al. and Hungerford et al. to immobilize the microdevice on the surface of the chip array as taught by Zhou et al. for high throughput analysis. One ordinary skill in the art would have been motivated to apply the microdevice for mass high throughput analysis by the format of array on biochip to take the advantage of economy and time-saving.

Response to Applicant's Arguments

5. Applicant argues that Kay et al. reference does not teach specifically a "binding partner" on the microdevice. Applicant argues that the peptide is not inherently a "binding partner". Applicant argues that Examiner has not shown Kay et al. reference teaching a compound on the microdevice, thus there can be no "necessarily present" inherent characteristics of a compound on which to base this rejection.

Applicant's arguments have been considered, but are not persuasive.

As shown by Kay et al., the microdevice disclosed was used for detection in chemical combinatorial library synthesis. Kay et al. teach that the microdevice can apply to various of compounds, including peptides, peptoids, carbohydrates, amino acid derivatives (See page 18, line 13-20). Kay et al. teach immobilizing these compounds on the microdevice. Take peptide for example, it is well known that peptide is capable of binding to a moiety, e.g. antibody specific for this particular peptide, based on antibody-antigen (peptide) binding relationship. Thus, it is a reasonable interpretation that the immobilized peptide is a binding partner.

6. Applicant also argues that claim 122 (now amended and claims 123-132 depend on claim 122) has feature of "patterned magnetic material" which distinguishes from the combination of Kay and Wu et al., particularly Wu et al. do not disclose "a patterned material".

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Applicant's arguments have been considered and are found persuasive. It is noted that none of the reference teaches using "a patterned magnetic material" on the microdevice. Nevertheless, claim 122 is still under rejection of 35 USC 112, second paragraph as set forth in this Office Action (See above).

7. With respect to claim 14, although the previous Office Action indicating allowable subject matter of the substrate comprising a metal layer having "nickel or metal or CoTaZr alloy", such feature is rendered obvious in view of the new cited Hasegawa et al. and Hungerford et al. references since Wu et al. reference teaches using magnetic force for detection of target molecule and both Hasegawa et al. and Hungerford references provide advantage of using either Nickel metal or CoTaZr alloy for increasing detection sensitivity.

Allowable Subject Matter

8. Claims 122-132 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

9. The following is a statement of reasons for the indication of allowable subject matter: No prior art teaches or fairly suggests using a metal layer on a microdevice where the metal layer comprises a patterned magnetic material for recognition. Such patterned magnetic material has an encoding feature as indicia on the microdevice. The closest prior art is the Wu et al. reference where Wu et al. teach using magnetic beads for recognition and detection purpose. But the magnetic beads are not manufactured in an encoding fashion, i.e. patterned, as the instant recited claim.

10. The following references are considered by Examiner but are not used as prior art in this Office Action.

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Finucane et al. Biochemistry 1999 Vol. 38, page 11604-11612.

Villeneuve et al. J. Pharmacology & Toxicological Method 1998 Vol. 40, page 95-100.

Conclusion

11. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACOB CHEU whose telephone number is (571)272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jacob Cheu/
Examiner, Art Unit 1641

/Long V Le/
Supervisory Patent Examiner, Art Unit 1641